

**ENVIRONMENTAL ASSESSMENT
GENERAL ELECTRIC COMPANY FOOD CONTACT NOTIFICATION**

1. **Date:** May 7, 2007
2. **Name of Applicant/Notifier:** General Electric Company
3. **Address:** 1 Noryl Avenue
Selkirk, New York 12158

All communications on this matter are to be sent in care of Counsel for Notifier:
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4. **Description of the Proposed Action**

The action requested in this notification is to establish the clearance of the food-contact substance (FCS) that is referred to as ULTEM® U2 Polymer, for use in the fabrication of food-contact articles. With the clearance of this Food-Contact Notification (FCN), the FCS will be used in contact with all food types under Conditions of Use J, as set forth in Tables 1 and 2, respectively. FDA's Condition of Use J corresponds to food-contact applications associated with "Cooking (e.g., baking or browning) at temperatures exceeding 250° F (121°C)."

The subject resin offers several technical properties that make it useful in a variety of food-contact applications. In particular, it provides good strength and rigidity at elevated temperatures, long-term heat resistance, high dimensional stability, and excellent chemical resistance. Thus, while broad clearance, including single use food-contact applications, is being sought in this FCN, the primary food-contact applications in which the FCS will be used, from a practical standpoint, are repeated use food-contact applications, given the beneficial mechanical properties of the resin; this is in keeping with the broader class of polyetherimide resins that are permitted for use in food-contact applications, *i e*, they, too, are used primarily in repeated-use applications even though they may be permitted to be use in contact with food more broadly.

The Notifier does not intend to produce finished food packaging from the subject resin. Rather, the resin will be sold to manufacturers engaged in the production of food-contact articles. The applications currently of interest are primarily articles used for repeated-use contact with food, such as steam trays, utensils, food trays, beverage dispensers, and commercial bakeware.

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At this time, due to the higher cost per pound of the subject polymer as compared to the cost of polymers currently used for single-use applications, the food-contact substance (FCS) is not commercially sold into single use applications. Therefore, examples of single use food-contact articles have not yet been identified; the FCN seeks clearance for the use of the FCS in both single-use and repeated-use applications so as not to preclude its potential future uses. Food-contact articles produced with the resin will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of the subject resin will occur nationwide, with the material being land disposed or combusted; it is not anticipated that the resin will be used in applications that will compete with or displace food-contact articles that are currently being recycled. According to the U S Environmental Protection Agency's (EPA) 2005 update regarding municipal solid waste in the United States, 54.3% of municipal solid waste generally was land disposed, 13.6% was combusted, and 32.1% was recovered for recycling and composting.¹

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the resin.

5. Identification of Substance that is the Subject of the Proposed Action

The FCS that is the subject of this notification is a copolymer of 1,3-benzenediamine (CAS Reg. No. 108-45-2), 1,3-isobenzofurandione, 4-chloro (CAS Reg. No. 117-21-5), 1,3-isobenzofurandione, 5-chloro (CAS Reg. No. 118-45-6) and 4,4'- isopropylidenediphenol (CAS Reg. No. 80-05-7); the FCS also may be referred to as poly[(bis(isoindol-2-yl)-1,3-dione)-1,3-phenylene)-4,4'-(1-methylethylidene)bisphenol].

The resin is marketed under the trade name ULTEM® U2 Polymer.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the resin. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

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¹ *Municipal Solid Waste in the United States 2005 Facts and Figures*, EPA530-R-06-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2006.

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No environmental release is expected upon the use of the subject resin to fabricate food-contact articles. In these applications, the resin is expected to be used as the basic polymer to fabricate all forms of food-contact articles, and will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact articles produced from the subject resin will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The resin consists primarily of carbon, hydrogen, and oxygen, with a small amount of nitrogen and a very small amount of chlorine. General Electric Company calculates that, based on the elemental composition of the FCS, the nitrogen and chlorine contents in the food-contact substance are 4.7% and %, respectively. With regard to carbon, hydrogen, and oxygen, these are elements that are commonly found in municipal solid waste. With regard to nitrogen and chlorine, these elements could potentially form combustion products that could be toxic at levels much higher than could be present from combustion of this FCS. Based on the proposed use of the food-contact substance, the anticipated market volume (available in a confidential attachment to the FCN), and calculations regarding the maximum introduced levels of nitrogen or chlorine containing combustion products (available in a confidential attachment to the FCN), we have concluded that the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the food-contact substance will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

Only extremely small amounts, if any, of the resin constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems. 40 C.F.R. Part 258. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate. The lack of any leaching is especially true considering that the subject substances are high molecular weight polymers that contain only minute levels of extractable material.

7. Fate of Emitted Substances in the Environment

(a) Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the resin. The polymers are of high

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molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the resin.

As indicated above in item 6, the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the food-contact substance will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

(b) Water

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject resin. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymers, nor upon its disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

(c) Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject resin. In particular, the extremely low levels of maximum migration of components of the resin, demonstrated by the extraction studies, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the low production of the resin for use in food-contact applications precludes any substantial release to the environment of their components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the resin.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the resin in the manufacture of articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food-contact articles fabricated with the use of the resin consist of extremely small quantities of combustion products and extractables. As discussed in the FCN, the monomers from which the resin is manufactured are not considered to present a substantive genotoxicity or carcinogenicity risk at the minute levels at which they may enter the diet. Furthermore, it is generally recognized that oligomeric substances are of lower potential toxicity than the monomers from which they are produced. Consequently, based on the absence of any concern vis-à-vis the monomers, the oligomers also are not expected to present any toxicological concern. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the resin. In addition,

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the use and disposal of the resin are not expected to threaten a violation of applicable laws and regulations, *e g* , the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors, and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use and disposal of the resin involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject resin in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the resin is intended to be used in food-contact articles which will be used in place of similar materials now on the market for use in food-contact applications. Polymers currently used in the applications in which Ultem® U2 Polymer is anticipated to be used include other polyetherimide resins and other engineering thermoplastic resins, examples of which are available in a confidential attachment to the FCN.

The replacement of these types of materials by the resin is not expected to have any adverse impact on the use of energy and resources. Manufacture of the resin, and its conversion to finished food-contact articles, will consume energy and resources in amounts comparable to the manufacture and use of the other polymers. While the clearance requested in this FCN involves use of the resin in any food-contact article used for cooking food, the food-contact applications in which the resin is most likely to be used are repeated use applications; it is unlikely that the subject resin will be used to fabricate bottles or have any significant use in other single use food-contact applications, especially as polyetherimide resins are much more expensive than the polymers currently used to fabricate single use food containers, particularly polyethylene terephthalate (PET) or high density polyethylene (HDPE). Price information regarding the food-contact substance as compared to PET and HDPE is available in a confidential attachment to the FCN. For this reason, the subject resin is not expected to be used as a replacement for PET in soda bottles or HDPE in milk bottles. As PET and HDPE bottles are the predominant food packaging articles recovered for recycling, and as Ultem® U2 Polymer will not be used in such applications, articles fabricated from the subject resin will be disposed of by means of sanitary landfill and incineration. Packaging materials produced from the resin are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future recycling programs.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the subject resin. This is primarily due to the minute levels of leaching of potential migrants from finished food-contact articles, the insignificant impact on environmental concentrations of combustion products of the resin, and the insignificant impact on the use of resources and energy when compared with the materials they are intended to replace. Thus, the use of the resin as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

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11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject resin would otherwise replace; such action would have no environmental impact. In view of the fact that the resin components are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from their use, the establishment of an effective Food Contact Notification to permit the use of the subject resin as described herein is environmentally safe in every respect.

12. List of Preparers

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Lester Borodinsky, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.

Date: 5/7/07



Joan Sylvain Baughan
Counsel for General Electric Company

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